

Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

Remarks

The foregoing amendments and following remarks are responsive to the March 22, 2007 Office Action. Reconsideration is respectfully requested.

Status of the Claims

Claims 19, 21-22, 26-27 and 31 are amended. Claim 23 is cancelled. Claims 1-18 were cancelled previously. Claims 19-22 and 24-38 are pending.

Rejection of the Drawings

The Examiner rejected the drawings as not illustrating all the elements in the claims. Specifically, the Examiner indicated that the processing element, the recording element, and the microprocessor are not shown. Element 7 is a processing element, which may consist of one or more filters or one or more analog/digital converters (page 11, lines 6-7 and page 15, lines 20-24 of the specification). Element 8 is a microprocessor/computer equipped with software for processing digital signals transmitted to it, and creates and displays (through a display screen) the curves representing the variations of the amplitude of the nerve potential as a function of time (page 16, lines 12-15 of the specification). The microprocessor/computer necessarily includes a recording element (memory). Therefore, contrary to the Examiner's allegation, the processing element, identified as element 7, and the recording element and microprocessor, identified together as element 8, are illustrated.

In reviewing the drawings, it was noted that the display associated with the microprocessor/computer did not have a reference numeral. Therefore, Figures 1 and 3 have been amended to include reference numeral 16 for the display. Support for the amendment is found in the specification on page 9, line 30 to page 10, line 2; page 14, line 29 to page 15, line 1; and page 16, lines 12-15. No new matter is added.

Replacement Sheets for Figures 1 and 3 are attached hereto. Approval and entry of the proposed amendments to the Figures are respectfully requested.

Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

Support for Amendment to the Specification

The specification is amended to include reference numeral 16 for the display associated with the microprocessor. Support for the amendment is found in the specification on page 9, line 30 to page 10, line 2; page 14, line 29 to page 15, line 1; and page 16, lines 12-15, and Figures 1 and 3. No new matter is added. Approval and entry of the proposed amendment to the specification are respectfully requested.

Support for Amendments/Added Claims

Claims 19 and 27 are amended to clarify the invention. Claims 21-22 and 26, and 31 are amended to reflect the amendments made to Claims 19 and 27, respectively. Support for the amendments to Claims 19 and 27 is found in the specification on page 1, lines 1-3; page 8, lines 16-19; page 9, line 19 to page 10, line 7; page 14, line 16 to page 15, line 1; and page 16, lines 12-15. No new matter is added.

Rejections under 35 U.S.C. § 102(b)

Claims 19-21, 26-27, 31-32 and 38 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,540,235 (Wilson). Claim 19 (from which Claims 20-21 and 26 depend), and Claim 27 (from which Claims 31-32 and 38 depend) are amended to clarify the invention.

Applicants' invention relates to a process and apparatus for the non-invasive *in vivo* characterization and analysis of the reactivity and/or hypersensitivity of a skin zone on the face by determining the conductivity of the nerves in the facial region.

Wilson relates to an adaptor for neurophysiological monitoring with a personal computer. The monitoring system includes a first detection circuit connected to a power supply for allowing detection of analog neurophysiological signals at a first site on a patient, a data processing circuit for amplifying analog signals and converting to digital signals, and an output device for sending the digital signals to a personal

Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

computer for further processing. The system also includes a second detection circuit connected to the data processing circuit for allowing detection of analog signals at a second site on the patient, and may also include a stimulation device connected to the power supply for administering a neurophysiological stimulation to the patient.

Wilson does not specifically disclose electrodes on the facial area, but discloses electrodes on the "head" (col. 5, lines 12-13) and scalp (col. 9, lines 39-40). It appears that the word "head" is a typographical error, because the electrodes are attached to a "hand" (reference numeral 13) in the Figures. None of the Figures in Wilson depicts electrodes attached to any part of a patient's head.

For a reference to anticipate, each element of the claim must be present. Since Wilson fails to disclose electrodes on the facial area as in Claims 19 and 27, Wilson does not anticipate the subject matter of the above claims, and the rejection should be withdrawn. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Under 35 U.S.C. § 103(a), Claim 22 was rejected as being unpatentable over Wilson in view of U.S. Publication No. 2004/0106877 (Denda); Claims 23-25 and 30 were rejected as being unpatentable over Wilson in view of U.S. Patent Publication 2003/0045922 (Northrup); Claims 28-29 were rejected as being unpatentable over Wilson in view of U.S. Patent No. 5,003,978 (Dunseath); Claims 33-35 were rejected as unpatentable over Wilson in view of U.S. Patent No. 6,026,321 (Miyata); and Claims 36-37 were rejected as being unpatentable over Wilson in view of Miyata and further in view of U.S. Patent No. 4,257,010 (Bergman).

Rejection based on Wilson and Denda

The Examiner alleges, with regard to Claim 22, that Wilson does not disclose further subjecting the skin substrate to a stress, and that Denda discloses this aspect.

Denda relates to a method and device for determining, *in vitro*, the condition of a

Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

skin surface. The method includes floating a section of skin on the surface of a culture solution and measuring a potential difference between the skin surface and the culture solution. The method further includes imparting stimulation to the skin surface to determine the difference between the potential difference (when no stimulation is imparted) and the measured potential difference. The apparatus for measuring the condition of the skin surface includes a standard electrode communicating with the culture solution, a measuring electrode communicating with the skin surface, and a potential difference detector for detecting the potential difference between the standard and measuring electrodes.

Wilson fails to disclose, teach, suggest, or provide motivation to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*. Denda fails to disclose, teach, suggest, or provide motivation for determination of the conductivity of nerves *in vivo*. Since there is no teaching, suggestion, or motivation provided by either reference to detect electrical signals from the facial region and determine the conductivity of the nerves *in vivo*, the rejection should be withdrawn. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection based on Wilson and Northrup

The Examiner alleges, with regard to Claims 23-25, that Wilson does not disclose a first non-invasive electrode positioned on a facial skin to transmit signals representative of electrical activity of at least one branch of a facial trigeminal nerve, and that Northrup discloses this aspect. The Examiner further alleges that Northrup does not explicitly disclose electrical contact with the maxillary branch, but that it would be obvious to one skilled in the art to place the electrodes in the position to gather information about the facial nerves for subsequent treatment. With regard to Claim 30, the Examiner alleges that Wilson does not disclose at least one non-invasive measuring electrode connected to an adjustable/adaptable holder, and that Northrup discloses this aspect.

Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

Northrup discloses a skin treatment method and apparatus. The method includes positioning electrode pairs on the face to stimulate nerves and to treat the face to improve facial contour, and diminish fine lines and wrinkles. Northrup does not disclose determining the conductivity of nerves in the facial region. Instead, Northrup only stimulates the nerves in the facial area.

As set forth above, Wilson fails to disclose, teach, suggest, or provide motivation to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*. In addition, Northrup fails to teach, suggest, or provide motivation to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*. Instead, Northrup merely stimulates the nerves as a method of treatment. Since there is no teaching, suggestion, or motivation provided by either reference to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*, the rejection should be withdrawn. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection based on Wilson and Dunseath

The Examiner alleges, with regard to Claims 28-29, that Wilson does not disclose the electrode as being non-polarizable, or comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof, and that Dunseath discloses this aspect.

Dunseath relates to a non-polarizable dry biomedical electrode for detection of biopotentials on the surface of a skin of a living body. The dry electrode includes a conductive substrate with a conductive adhesive. The conductive adhesive may include a mixture of finely ground silver and silver chloride powders loaded into a polymeric material. Other conductive loading materials that form a reversible junction when in contact with saline solutions include titanium hydroxide, or mixtures of titanium hydride, silver chloride, sodium tungstate dihydride and graphite.

As set forth above, Wilson fails to disclose, teach, suggest, or provide motivation

Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*. The disclosure by Dunseath of various conductive materials (none of which includes stainless steel as alleged by the Examiner) does not cure the deficiencies of Wilson. Since there is no teaching, suggestion, or motivation provided by either reference to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*, the rejection should be withdrawn. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection based on Wilson and Miyata

The Examiner alleges, with regard to Claims 33-35, that Wilson does not disclose at least one preamplifier with a high input impedance over a voltage range of from -3 to +3 volts, and that Miyata discloses this aspect.

Miyata relates to an apparatus and system for measuring electrical potential variation in a human body. The apparatus includes a pair of conductors, an amplifier, transmitter, a voltage-divider circuit, and a compensator circuit. Miyata does not measure conductivity of nerves on a skin substrate, but instead measures myoelectric (muscle) potentials.

As set forth above, Wilson fails to disclose, teach, suggest, or provide motivation to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*. The disclosure by Miyata of a preamplifier does not cure the deficiencies of Wilson. Since there is no teaching, suggestion, or motivation provided by either reference to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*, the rejection should be withdrawn. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection based on Wilson and Miyata and Bergman

The Examiner alleges, with regard to Claims 36-37, that Wilson, modified by Miyata, discloses at least one preamplifier connected to the non-invasive measuring

Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

electrode, but does not disclose the at least one preamplifier connected to the non-invasive measuring electrode by a shielded cable, and that Bergman discloses connecting wires surrounded by a shielding to prevent interference.

Bergman relates to a method and apparatus for sensing and maintaining oscillations in an oscillating system. The apparatus includes a signal transmitter.

As set forth above, Wilson fails to disclose, teach, suggest, or provide motivation to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*. The disclosure by Miyata of a preamplifier does not cure the deficiencies of Wilson. The additional disclosure by Bergman of shielded wires does not cure the deficiencies of Miyata and Wilson. Since there is no teaching, suggestion, or motivation provided by any of the references to detect electrical signals from the facial region and determine the conductivity of nerves *in vivo*, the rejection should be withdrawn. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Fees

No fees are believed due, but the Commissioner is authorized to charge any fees deemed due (or credit any balance) to Deposit Account No. 50-1177.


Appl. No. 10/530,811
Group Art Unit: 3736
Reply to March 22, 2007 Office Action

Conclusion

It is respectfully submitted that Claims 19-22 and 24-38 are in condition for allowance. A Notice of Allowance is respectfully requested. If anything further is needed to advance the allowance of this application, the Examiner is respectfully requested to contact Applicants' attorney at the telephone number indicated below.

Respectfully submitted,

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Enclosure: Replacement Sheets for Figures 1 and 3 (2 pgs.)

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